Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

[48 FR 40703, Sept. 9, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 27489, July 5, 1984; 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997; 64 FR 56448, Oct. 20, 1999; 65 FR 34962, June 1, 2000]

§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14934, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

§ 5.60 Required and discretionary postmarket surveillance.

(a) For any device (including any device that is or contains a drug or biologic) that was first introduced or delivered for introduction into interstate commerce after January 1, 1991, and that is either a permanent implant, the failure of which may cause serious adverse health consequences or death, a life-sustaining or life-supporting device, or a device that potentially presents a serious risk to human health, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Division Directors and Associate Division Directors, Office of Device Evaluation, CDRH.

(5) The Chief, Premarket Notification Section; Chief, Premarket Approval Section; Director, Program Operations Staff, Office of Device Evaluation, CDRH.

(6) The Director and Deputy Director, Office of Compliance, CDRH.

(7) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(8) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(9) The Director and Deputy Director, Office of Compliance, CDER.

(10) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(11) The Director and Deputy Director, Office of Compliance, CBER.

(12) The Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For any device (including any device that is or contains a drug or biologic), any of the following officials is

authorized to require a manufacturer of a device to conduct postmarket surveillance if the official determines that postmarket surveillance of the device is necessary to protect the public health or provide safety or effectiveness data for the device:

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Compliance, CDRH.

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(7) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(8) The Director and Deputy Director, Office of Compliance, CDER.

(9) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(10) The Director and Deputy Director, Office of Compliance, CBER.

(11) The Director and Deputy Director, Office of Biological Product Review, CBER.

[57 FR 40315, Sept. 3, 1992, as amended at 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Premarket Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under sections 409 and 721 of the act regarding the approval of the use of food additives under section 409(e) of the act and the listing of color additives under section 721(d) of the act where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under § 130.17 of this chapter:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner of Food and Drugs regarding approvals of the